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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,393 | 01/12/2007 | Patrick Holt | 65138(53253) | 9686 |

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| EXAMINER | |
|---|---|
| JUEDES, AMY E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/574,393 | HOLT ET AL. | |
| | Examiner | Art Unit | |
| | AMY E. JUEDES | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33 and 50-61* is/are pending in the application.

4a) Of the above claim(s) *2,9,11,12,14-18,20-26,30 and 50-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10,19,27-29 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's amendment and remarks, filed 3/20/10, are acknowledged.

Claims 13 and 21 have been amended.

Claims 52-61 have been added.

Claims 1-33 and 50-61 are pending.

Claims 2, 9, 11-12, 14-18, 20, 22-23, 25-26, 30 and 50 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that amended claims 13, 21, 24, and 51 and new claims 52-61 are being withdrawn from further consideration as being drawn to a non-elected species. Said claims are drawn to a method comprising administering a Th2 adjuvant, and Applicant has elected the species of method comprising administering a Th1 adjuvant.

Claims 1, 3-8, 10, 19, 27-29, and 31-33 are being acted upon.

2. The objection to the drawings is withdrawn in view of Applicant's submission of a corrected version of Fig. 4 on 3/2/10.

3. In view of Applicant's amendment and the withdrawal of claims 13, 21, 24, and 51, the rejection under 35 U.S.C. 112 first paragraph and 35 U.S.C. 103 is withdrawn.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-6, 19, 27-28, and 31-33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Franco et al., 1998.

As set forth previously, Franco et al. teach a method for reducing a Th2 immune response to an antigen (i.e. a method of treating an antigen specific allergic reaction) comprising administering an antigen via the

oral route (i.e. in immunotherapeutic form) and subsequently administering the antigen in CFA by a subcutaneous injection (i.e. in immunogenic form comprising a Th1 adjuvant). Franco et al. teach performing the method in mice, which can be considered "livestock". Franco et al. teach administering 5 doses of the antigen via the oral route, and 1 dose of the antigen in CFA (see page 2, in particular). Franco et al. teach that the oral antigen is administered with a syringe and can thus be considered an "injection", see page 2 in particular). Franco et al. teach administering the antigen (DNP) attached to a carrier protein (i.e. an "agent" designed to modulate the specific immune response, see page 2 in particular). Additionally, the method of Franco et al. results in a reduction in a Th2 immune response to the antigen compared to an animal not receiving the oral antigen, and it can be considered a method of treating a Th2 mediated allergic response against said antigen. (i.e. an atopic disorder or disease) .

Applicant's arguments filed 3/2/10 have been fully considered, but they are not persuasive.

Applicant argues that Franco et al. discloses inducing oral tolerance in mice that have not been sensitized to the antigen. Thus, Applicant concludes that the mice of Franco et al. do not have a "Th2 associated disease" as required by the instant claims.

The instant claims do not require administering the antigen to a subject having a "Th2 associated disease". Rather claim 1 is drawn to a method of altering a specific immune response to an antigen in an individual sensitized to the antigen. Franco et al. teach administering the antigen by the oral route 5 times. Therefore, some of the doses of the antigen have been administered to an individual previously exposed to the antigen (i.e. Franco teaches administering to a "sensitized" individual). Similarly, claim 21 is drawn to a method comprising administering antigen to an individual in need of immunotherapy, and not to a subject having a Th2 associated disease. The mice of Franco et al. can be considered to be "in need" of immunotherapy.

6. Claims 1, 3-8, 10, 19, and 27-29 stand rejected under 35 U.S.C. 102(b) as being anticipated by Drachenberg et al., 2001.

As set forth previously, Drachenberg et al. teach a method of immunotherapy for treating pollen specific allergy comprising administering low doses of pollen allergen and MPL adjuvant (i.e. an "immunotherapeutic" dose) followed by administration of high doses of pollen allergen and MPL adjuvant (i.e. an "immunogenic" form of the antigen comprising a Th1 adjuvant, see page 500 in particular). Drachenberg et al. teach that the method functions by changing the T cell cytokine profiles from a Th2 to a Th1 type (see page 502, in particular). Drachenberg et al. teach performing the method in a human (i.e. a primate, see page 500 in particular). Drachenberg et al. teach including the MPL adjuvant in the lower doses (i.e. an immunotherapeutic form further comprising an

agent designed to modulate the specific immune response). Drachenberg et al. teach administering several doses of the antigen (see page 500 in particular).

Applicant's arguments filed 3/2/10 have been fully considered, but they are not persuasive.

Applicant argues that Drachenberg does not teach the step of "administering to the individual still under the effects of immunotherpy an effective amount of an immunomodifying agent comprising said antigen in immunogenic form and Th2 adjuvant'", as recited in claims 13 and 21.

However, claims 13 and 21 have been withdrawn from consideration as being drawn to non-elected species, and the claims rejected above are not limited in this regard.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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